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C-621/15 - W AND OTHERS v SANOFI PASTEUR: AN EXAMPLE OF JUDICIAL DISTORTION AND INDIFFERENCE TO SCIENCE

Summary: This case commentary examines the CJEU's recent decision in Case 621/15 *W and Others v Sanofi Pasteur MSD SNC* [2017] ECR I. This commentary critically examines the decision through the lens of the cultural conflict between law and science. We argue that the CJEU's decision reflects both a distortion of scientific knowledge and an improper indifference to the legitimate methods by which scientific knowledge is generated in the context of vaccines. These judicial approaches may, the authors argue, inadvertently fuel the vaccine scepticism that is growing across the developed world, and in particular in Europe.

Keywords: CJEU; Hepatitis B; Multiple Sclerosis; products liability; tort; vaccines.

I. INTRODUCTION

Vaccines are biological pharmaceuticals that produce or improve immunity against a specific disease. Vaccines contain bacteria or viruses that are known to cause a particular infection, such as Hepatitis B and, once administered, work by imitating the relevant infection without causing illness to the individual. This allows the individual's immune system to develop the same response as it would if they were naturally infected with the infection; thereby priming their immune system to fight the infection. Vaccines are vital public health tools as the beneficial effects of them are not just felt by the individual receiving the vaccine, but by those in the wider community too, through herd immunity.[1]

As vaccines are typically administered to healthy individuals, and have the possibility to cause harm through adverse events, various legal frameworks control their development, licensing, and regulation. Vaccine development involves multiple stages (including pre-clinical trials and phased clinical trials)[2], all of which primarily focus on the ability of the vaccine manufacturer to demonstrate that the vaccine is safe and efficacious.[3] If clinical trials do prove (to the required level of scientific certainty) that a vaccine can prevent disease, and that vaccine is subsequently

[1] C Gordon E Smith, 'Prospects for the control of infectious disease' (1970) 63(11) Proc R Soc Med 1181; JP Fox and others, 'Herd immunity: Basic concept and relevance to public health immunization practices' (1971) 94(3) American journal of epidemiology 179 ; Paul Fine, 'Herd immunity: History, theory, practice' (1993) 15(2) Epidemiologic reviews 265 ; David L Heymann and R. B. Alyward, 'Mass Vaccination in Public Health' in David L Heymann (ed), *Control of communicable diseases manual* (19th edn, American Public Health Association 2008)

[2] ME Halloran, IM Longini, CJ Struchiner, Design and analysis of vaccine studies. (Springer, New York, 2010)

[3] *ibid.*

administered to the wider public, on-going monitoring will occur through pharmacovigilance activities.[4] In France, the jurisdiction from which *C-621/15* was referred, this is undertaken by *'Agence nationale de se´curite´ du me´dicament et des produits de sante´'* (ANSM) during clinical trials.[5] Pharmacovigilance provides "strict safety supervision" of vaccines by detecting, assessing, understanding, preventing, and communicating any adverse events that follow immunisation.[6] An 'adverse event' refers to harm caused by a vaccine beyond 'normal' side effects.[7]

When an 'adverse event' occurs, the science underpinning vaccines may eventually intersect with the law in the context of the tort of products liability. In such instances, an individual subject to the adverse event (or their next of kin) may seek compensation for the harm sustained from the producer of the vaccine. In order to receive compensation, the claimant will need to satisfy relevant legal rules related to that tort.[8] For member states of the European Union, Article 4 of Directive 85/374 ('the Directive') provides for producer liability where a product is deemed "defective", providing the injured person can prove "the damage, the defect and the causal relationship between the defect and damage".[9] It is in this context that *C-621/15* arose. In *C-621/15* France sought clarification from the Court of Justice of the European Union (CJEU) about how to, in accordance with the Directive, approach an alleged causal relationship between the Hepatitis B vaccine and the onset of Multiple Sclerosis (MS); compelling the CJEU to consider the science underpinning the vaccine within its system of legal rules and ideals.

This comment examines the CJEU's decision in *C-621/15*. Part II provides a case history including the history of legal claims, questions referred to the CJEU and the associated findings of that court. Part III critically examines the CJEU's decision through the lens that this case is, in the authors' view, a compelling example of the cultural conflicts that beset the institutions of law and science when they intersect in this way. Specifically, the authors argue the CJEU's decision reflects both a distortion of scientific knowledge (particularly about the alleged causal relationship between Hepatitis B vaccine and the onset of MS), and an improper indifference to the legitimate methods

[4] World Health Organization, The importance of pharmacovigilance (WHO, Geneva, 2002). Available at: http://apps.who.int/iris/bitstream/10665/42493/1/a75646.pdf (last accessed 05/09/2017)

[5] P Peretti-Watel, et al, 'Vaccine hesitancy: clarifying a theoretical framework for an ambiguous notion' (2015) 25 PLoS currents 7

[6] World Health Organization, (n4)

[7] World Health Organization, (n4), P.40

[8] This varies from jurisdiction to jurisdiction. For comparison the US system of product liability related to vaccines operates as a no-fault liability scheme,. For more information see: KM Cook & G Evans, 'The national vaccine injury compensation program' (2011) 4 Paediatrics 146

[9] Directive 85/374 93/104 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] 85/374/EEC (Products Liability Directive)

by which scientific knowledge is generated in the context of vaccines. These judicial approaches may, the authors argue, inadvertently (but no less worryingly) fuel the vaccine scepticism that is growing across the developed world, and in particular in Europe.

II: CASE HISTORY

C-621/15 arose from events concerning a 'Mr W' in France. Mr W was vaccinated against Hepatitis B through the administration of three separate injections following a mass vaccination campaign in France.[10] Sanofi Pasteur (Sanofi) manufactured the three doses Mr. W received, the last of which was administered on 8th July 1999.[11] In August 1999, Mr. W "began to present with various troubles."[12] In November 2000, fifteen months after receiving his first Hepatitis B vaccination,[13] he was diagnosed with MS.[14] His health worsened to the point that he required constant care, and he died on 30th October 2011.[15] Prior to his death, Mr. W and three family members instigated legal proceedings against Sanofi arguing the Hepatitis B vaccine was defective and there was a causal relationship between the vaccine and the onset of Mr. W's MS.

A. History of Legal Claims

The initial action and first appeal

In 2006, Mr W brought an action, relying on Article 136-1 (now Article 1245-8) of the French Civil Code, arguing that Sanofi should compensate them for the "damage" caused to Mr W as a result of him being administered the Hepatitis B vaccine.[16] They claimed two particular facts gave rise to "serious, specific and consistent presumptions" as to the vaccine being defective and there being a causal relationship between the Hepatitis B vaccine and Mr. W's onset of MS. These facts were the (1) "short period between the vaccination and the appearance of the first symptom of multiple

[10] MA Balinska, 'Hepatitis B vaccination and French Society ten years after the suspension of the vaccination campaign: how should we raise infant immunization coverage rates?' (2009) 46 Journal of Clinical Virology 3, 202-205; F Denis & D Levy-Bruhl, Mass Vaccination Against Hepatitis B: The French Example, (Springer, New York, 2006)
[11] Case 621:15 *W and Others v Sanofi Pasteur MSD SNC* [2017] ECR I – 1 484, para 9.
[12] *ibid*, para 9.
[13] *ibid*, para 9.
[14] *ibid*, para 9.
[15] *ibid*, para 10.
[16] *ibid*, para 10.

sclerosis"; and (2) "lack of any personal or family history of the disease".[17] A decision from the Cour de Cassation (French Court of Causation) provided that a court ruling on the merits may consider such facts when determining a 'defect' and causal relationship.[18] This was the case regardless of whether "medical research establishe[s] a relationship between the vaccine and the occurrence of the disease".[19] This action was upheld at first instance by Tribunal de Grande Instance de Nanterre (Regional Court, Nanterre, France) on September 4, 2009. Sanofi appealed to the Cour d' appel de Versailles (Court of Appeal, Versailles), who overturned the decision on 10th February, 2011, finding the presumptions were capable of providing a causal relationship, but not a defect in the vaccine.[20]

The second and third appeals

W appealed to the Cour de Cassation, who found in his favour on 26th September, 2012. The Court found that "general considerations," such as the "cost/benefit ratio of the vaccination"; Mr W's excellent health pre-vaccination; the lack of "family antecedents" with regards to MS; and the close temporal proximity between the vaccinations and onset of MS, meant serious, specific and consistent presumptions supporting the conclusion that there was causal link between the Hepatitis Vaccine and onset of MS was sufficiently established.[21] This was the case without examining whether the same presumptions were sufficient to show 'defect' too.[22]

Sanofi appealed the decision to the Cour d'appel de Paris (Court of Appeal, Paris, France), who overturned the judgement of the Tribunal de Grande Instance de Nanterre. In so ruling, the court made a number of observations. First, that there was no "scientific consensus" supporting a "causal relationship between the vaccination against hepatitis B and multiple sclerosis".[23] Specifically, the court noted, all the "national and international health authorities" had rejected the association between a likelihood of being affected by certain characteristics of MS and the Hepatitis B vaccine.[24] Second, the court stated that multiple medical studies show the aetiology of MS is currently "unknown".[25] Third, a recent medical publication concluded that, at the time when the "first symptoms of multiple sclerosis appear, the pathophysiological process probably commenced

[17] *ibid*, para 11.
[18] *ibid*, para 13.
[19] *ibid*, para 13.
[20] *ibid*, para 14.
[21] *ibid*, para 15.
[22] *ibid*, para 15.
[23] *ibid*, para 16.
[24] *ibid*, para 16.
[25] *ibid*, para 16.

many months or many years earlier".[26] Fourth, epidemiological studies show that "92 to 95%" of persons suffering from MS had no family history of the disease.[27] On the basis of these observations, the Court concluded the factors relied upon by W could not "together or separately" establish serious, specific and consistent presumptions that there was a causal relationship between the Hepatitis B vaccine and the onset of W's MS.

Referral to the Court of Justice of the European Union

W appealed against the ruling of the Cour d'appel de Paris. The Cour de Cassation stayed proceedings and referred three questions to the CJEU for preliminary ruling. In summary, these questions were:

1. In the context of pharmaceutical vaccine manufacturer liability, does the Directive prevent a court from relying upon the evidence presented by W when determining liability (*i.e.* what constitutes "serious, specific and consistent presumptions" to show a defect and causal relationship), notwithstanding that medical research does not establish a "causal relationship" between a vaccine and the injury (*i.e.*, there is no scientific consensus)?

2. Does the Directive prevent Member States from creating a system of "presumptions" with respect to vaccine injuries, where, if certain "indications of causation" are found, liability always follows (regardless of "scientific consensus")?

3. Does the Directive require that a victim must adduce evidence that a "causal relationship" between the vaccine and the injury is scientifically established (*i.e.*, there is a scientific consensus as to causation)?[28]

B. Findings of the CJEU.

The CJEU made rulings in respect of questions one and two, and found it unnecessary to consider the third. The CJEU's findings are summarised below.

Question 1

[26] *ibid*, para 16.
[27] *ibid*, para 16.
[28] *ibid*, para 17.

The court determined that the Directive does not prevent the use of evidence - such as that presented by W - for establishing a casual relationship between a vaccine and the onset of harm. In the absence of legislation dictating what evidence should be adduced,[29] member states should determine "how the evidence is to be elicited".[30] Member states must ensure that the evidence adduced in sufficiently serious, specific and consistent to warrant the conclusion that a defect is the most plausible explanation for the relevant damage, "with the result that the defect and the casual link may reasonably be considered established".[31] Ultimately, national courts can use evidence concerning temporal proximity between the administering of a vaccine and the occurrence of a disease; the lack of personal and familial history of that disease; and a "significant number of reported cases of the disease occurring following such vaccines being administered" to enable the victim to satisfy "his burden of proof under Article 4 of Directive 85/374".[32]

The court stated that "medical research neither confirms nor rules out a link between"[33] the administration of the Hepatitis B vaccine and the on-set of MS (which we return to below). As a consequence of this, they stated that evidentiary rules that, first, prevent the claimant from using "circumstantial evidence"[34] and, second, require certain evidence based on medical research in order for the victim to be able to discharge the burden of proof[35] would be contrary to the "effectiveness" of the Directive.[36]

Question 2

The court ruled that member states could not legislate to create their own systems of "pre-determined relevant evidence"[37] that would – in effect - establish automatic presumptions of a causal link between a vaccine defect and the onset of injury. To do so – the court observed - would undermine Article 4 of the Directive.[38] In particular, the court found such systems would deprive vaccine manufacturers of the chance to put forward "scientific arguments" to "rebut" those

[29] *ibid*, para 24.
[30] *ibid*, para 25.
[31] *ibid*, para 37.
[32] *ibid*, para 41.
[33] *ibid*, para 30.
[34] *ibid*, para 30.
[35] *ibid*, para 30.
[36] *ibid*, para 31.
[37] *ibid*, para 47.
[38] *ibid*, para 52.

presumptions.[39] Naturally, this would also mean a causal link is established before a court ruling on the merits of a case had the opportunity to consider the producer's evidence and arguments.[40]

Question 3

The CJEU did not consider question three because in light of it's ruling on question one, a causal link need not always be "scientifically established."

III: CRITICAL DISCUSSION

The judgement of the CJEU in *C-621/15* raises questions about how scientific knowledge is approached by the judicial process. In this context the authors have identified a number of issues for discussion. First however, we must address the general conflict between law and science, which *C-621/15* highlights in the specific context of judicial engagement with products of science (vaccines) and the scientific method underpinning those products.

Generally, science assists law to understand the world in which legal policy must operate:[41] shaping legal frameworks that govern society in various areas including the development, licensing, and regulation of medical products, such as vaccines. In so doing, science helps law to tackle complex societal challenges such as the regulation of public health. In many ways *C-621/15* is a classic intersection of law and science, namely the judiciary being asked to determine the legal response for when a product of science, namely a vaccine, has allegedly caused an adverse event. Such cases logically require the judiciary to confront scientific evidence as part of the decision making process. In such instances, it is natural for conflict or inconsistencies to emerge. This is primarily because law and science approach the world in different ways.

First, science cannot yield the levels of certainty that the legal process often believes it can. This is because science employs a method that is circular in nature, and therefore tends to be naturally progressive and forward-thinking.[42] This stands in stark contrast to the judicial process, which, through its reliance on precedent,[43] for example, is inherently inclined to look back and tie itself to

[39] *ibid*, para 53.

[40] *ibid*, para 53.

[41] DL Faigman, Legal Alchemy: The Use and Misuse of Science in the Law, (Henry Holt & Co, 2000) Faigman argues that "without [science], legal policy is literally blinded." p.6.

[42] S Jasanoff, 'Just Evidence: The Limits of Science in the Legal Process' (2006), 34 JL Med & Ethics 328, 334.

[43] Despite there not being a strict doctrine of precedent in EU law— the CJEU does appear to regard its previous decisions as being binding in some instances. See: A Toth, 'The authority of judgments of the European Court of

the past.[44] Second, science tends to produce provisional products of knowledge (or rather, dominant theories), whereas the judicial process demands finality and definite answers in order to resolve disputes while maintaining the efficacy of its processes and outcomes.[45] Third, the standards by which science and the judiciary will be persuaded of the 'truthfulness' of a claim differ: law imposes specific standards of proof that can proven in a variation of ways depending on the case at hand, whereas science, especially in the context of a pharmaceutical product like vaccines, has rigid frameworks that must be adhered to in order for an approximation of 'truth' to be considered valid.[46]

Institutions that have competence to address the intersection of law and science in the context of vaccines, such as the CJEU in *C-621/15*, must be mindful to not exacerbate these tensions through their decision-making, to the detriment of what science perceives truth to be - *i.e.* the relevant dominant theory. In the authors' view *C-621/15* showcases the judiciary doing just that. We make three observations in support of our viewpoint.

Our first point relates to how the CJEU describes competing scientific evidence. In *C-621/15*, the court states that "medical research neither confirms nor rules out a link between"[47] the administration of the Hepatitis B vaccine and the on-set of MS. Here, the court is seemingly making an observation about the general, current clinical evidence landscape that has investigated an alleged link between the Hepatitis B vaccine and the on-set of MS. In our view, the court's phrasing distorts the current scientific consensus produced through this body of research. The court's language suggests it views the research as being equally weighted about whether there is a link between the Hepatitis B vaccine and the on-set of MS. At present, however, although a few studies approximate a link,[48] and others have produced inconclusive results,[49] the vast majority of current

Justice: Binding force and legal effects' (1984) 4 *Yearbook of European Law* 1; J Komarek, 'Federal Elements in the Community Judicial System: Building Coherence in the Community Legal Order' (2005) 42 *CMLR* 9, 16

[44] SL Cooper, 'Forensic Science Identification Evidence: Tensions Between Law and Science' (2016) Journal of Philosophy, Science & Law, 16(4), 1-35. P.9

[45] *ibid*, P.11 ("…a strong fidelity to finality, precedent, and consistency in judicial decision-making are the order of legal business…")

[46] In the context of the EU see: European Medicines Agency, 'Applying for EU marketing authorisation For medicinal products for Human Use' (EU,Brussels, 2015) available at: http://www.ema.europa.eu/docs/en_GB/docment_library/Leaflet/2011/03/WC500104233.pdf (last accessed 04/09/2017)

[47] Case 621:15 *W and Others v Sanofi Pasteur* (n11), at paras 18, 30, 31, 43, 44, 55, 57.

[48] M Hernán, et al. 'Recombinant hepatitis B vaccine and the risk of multiple sclerosis A prospective study' (2004) Neurology 63(5), 838-842; D Le Houézec, 'Evolution of multiple sclerosis in France since the beginning of hepatitis B vaccination' (2014) 60 Immunologic research 2, 219-225.

[49] E Touzé et al. 'Hepatitis B vaccination and first central nervous system demyelinating event: a case-control study' (2002) 21 Neuroepidemiology 4 180-186; A Langer-Gould et al. 'Vaccines and the risk of multiple sclerosis and other central nervous system demyelinating diseases' (2014) 71 JAMA neurology 12, 1506-1513.

research supports a dominant theory that there is no scientifically valid link between the Hepatitis B vaccine and the on-set of MS.[50] Moreover, it is this theory that international and national institutions focused on safeguarding healthcare promulgate through their policies and guidelines.[51] The CJEU's approach to describing the research as neither confirming nor ruling out a link in *C-621/15* thus distorts the scientific reality. This distortion is not, however, an uncommon eventuality of scientific evidence being funnelled through legal processes, which can have the effect of "minimizing its [science's] rigour, care and professionalism in the process".[52]

This brings us to our second point: how the CJEU balances conflicting scientific evidence. In *C-621/15* the CJEU was presented with two conflicting sets of evidence. The first was that "all the national and international health authorities had rejected the association between a likelihood of being affected by central or peripheral demyelinating disease (characteristic of MS) and the vaccination of Hepatitis B."[53] The second body of evidence was based on the timing between the administration of the vaccine and the onset of MS in Mr W, the lack of family history of MS in Mr W's family, and the existence of a "significant number of reported cases of the disease occurring following such vaccines being administered".[54] Ultimately, whichever set of evidence the court felt most persuaded by would determine whether liability on the part of Sanofi could be established, such was the stark contrast between the competing sets of evidence. The decision in *C-621/15* implies that the court was more persuaded by the second set of evidence, than the first.

We find this approach concerning because, while the CJEU is not entirely dismissive of scientific evidence as a factor to be considered when determining the causal link between the administration of a vaccine and the onset of an injury, the judgment does present the court to be somewhat indifferent to the majority of scientific evidence in this field. More precisely, the court appears to be indifferent to the manner in which the scientific evidence regarding the safety of the vaccine was created, and the legitimacy the scientific method lends the results it creates.[55] In concluding that "administering of the vaccine is the most plausible explanation for the occurrence of the disease

[50] For a systemic review of both randomized clinical trials and non-randomized studies addressing the correlation between administration of a Hepatitis B vaccine and the onset of MS see: F Farez & J Correale, 'Immunizations and risk of multiple sclerosis: systematic review and meta-analysis' (2011) 258 *Journal of neurology* 7, 1197-1206.

[51] for example: World Health Organization, 'The Global Advisory Committee on Vaccine Safety rejects association between Hepatitis B vaccination and multiple sclerosis (MS)' (WHO, Geneva, 2002) available at: http://www.who.int/vaccine_safety/committee/topics/hepatitisb/ms/en/ (last accessed 04/09/2017)

[52] Cooper, (n44) P.8

[53] Case 621:15 *W and Others v Sanofi Pasteur* (n11), para 16.

[54] *ibid*, para 41.

[55] For an outline of this process, see: SA Plotkin, History of vaccine development (Springer, New York, 2011)

and, that the vaccine therefore does not offer the safety that one is entitled to expect"[56] the court placed a greater emphasis on the evidence related to the timing of the vaccine, and family history, than on the large body of scientific evidence that establishes there is no causal link between receiving a Hepatitis B vaccine, and the onset of MS. Our concern with the court's approach to this evidence is not that the court took into account the second body of evidence relating to proximity but rather, that the court presents that body of evidence as being equally convincing as the first set of evidence. Our point is that the body of relevant scientific evidence in this case should have been given greater deference. Instead however, the court seemingly gave greater deference to the circumstantial evidence presented.

We argue that the scientific evidence should have been given greater deference because of the method by which it was produced. The knowledge underpinning the position that there is no known association between a likelihood developing MS and the administration of a Hepatitis B vaccine is a result of the application of the scientific method to a particular hypothesis, i.e: "the administration of a Hepatitis B vaccine does not cause multiple sclerosis." This hypothesis is then tested against the data, though a process of systematic process of observation, and experimentation. The studies which demonstrate no link between the administration of a Hepatitis B vaccine and the onset of MS have several thousand study participants.[57] By contrast, the claim that the administration of the vaccine did cause Mr. W's MS is informed largely by a temporal correlation between administration and onset of the disease in the case study of Mr. W, as well as "significant number of reported cases of the disease occurring following such vaccines being administered".[58] In the case study of Mr. W, as well as the "significant number of reported cases", the individual sample size for each of these studies is likely to be one. It is improper to reach a conclusion regarding the causal link between the administration of a drug and an adverse event occurring on the basis of such small sample sizes. Indeed, the authors acknowledge that the small sample size limits the generalisability of these results [59] As Ankeney explains "Although cases are central to the epistemic practices utilized[sic] within clinical medicine, they appear to be limited in their ability to provide evidence about causal relations be- cause they provide detailed accounts of particular patients without

[56] Case 621:15 *W and Others v Sanofi Pasteur* (n11), para 41.

[57] Ascherio et al. 'Hepatitis B vaccination and the risk of multiple sclerosis' (2001) 334 *NEJM* 5, 327-332.; Mikaeloff, et al. 'Hepatitis B vaccination and the risk of childhood-onset multiple sclerosis' (2007) 161 *Archives of paediatrics & adolescent medicine* 12, 1176-1182; Sadovnick et al, 'School-based hepatitis B vaccination programme and adolescent multiple sclerosis' (2000) 355 *The Lancet* 9203 549-550.

[58] Case 621:15 *W and Others v Sanofi Pasteur* (n11), para 41.

[59] Herroelen, et al. 'Central-nervous-system demyelination after immunisation with recombinant hepatitis B vaccine' (1991) 338 The Lancet 8776, 1174-1175.

explicit filtering of those attributes most likely to be relevant for explaining the phenomena observed".[60]

The CJEU's approach to these competing bodies of evidence undermines the role of science in the court process. However, such an approach is not altogether surprising, courts often struggle to accurately address conflict within science. This struggle can be attributed to various factors, including that judges often lack scientific expertise, and that legal frameworks and ideals do not easily reconcile with the scientific method.[61] At the centre of this case was a challenge to the dominant theory (produced by the scientific method) that there is no causal relationship between the administration of a Hepatitis B vaccine, and the onset of MS. This is the generally accepted position of the scientific community. Mr W challenged this dominant theory through producing circumstantial evidence. Circumstantial evidence, such as this, is insufficient to persuade science to change a dominant theory, however, in *C-621/15* this evidence did persuade the court to sideline the dominant theory. In so doing, the CJEU injects legitimacy into the circumstantial evidence(s), absent there being a scientifically robust reason for doing so. This is not an atypical legal approach to science, however. As Jasanoff has explained, "the law accept[s] facts that science might still deem provisional … Scientific facts needed to resolve legal disputes frequently come into being only as those disputes unfold. They are not available before the fact in some convenient storehouse of relevant, well-documented, yet case-specific facts".[62]

In addition to this even when the CJEU does engage with the role of 'science' in determining products liability claims in the context of vaccines - the CJEU undersells the importance of science. In *C-621/15* the CJEU rejects the implementation of systems that comprise irrefutable presumptions *i.e.*, systems that automatically presume a causal relationship exists when certain facts are established. The CJEU's rejection is based on a concern that,

> such a presumption would have the consequence that, even where the pre-identified facts are not, hypothetically, capable of establishing with certainty the existence of such a causal link, the producer would, in such a case, be deprived of all opportunity to adduce facts or put forward arguments, such as scientific arguments, in order to rebut that presumption, and the

[60] Ankeny, 'The Overlooked Role of Cases in Casual Attribution in Medicine' (2014) 81 Philosophy of Science 5, 999-1011
[61] SL Cooper, (n44)
[62] S Jasanoff, (n42)

court would thus not have any opportunity to assess the facts in the light of that evidence or those arguments.[63]

The CJEU's comment agrees that science is relevant to disputes such as the instant, and implicitly accepts that science may progress *i.e.*, research may be produced to rule out and/or establish causal relationships. We applaud the CJEU for singling out 'scientific arguments' in determining this question. However, we also take the view that the court should have been more direct regarding the role of science in determining such issues *i.e.*, made the weight of scientific consensus a key factor to be considered in every such dispute.

Our final point is that the CJEU's overall approach in *C-621/15* generally feeds the growing vaccine skepticism in the developed world, particularly in France. Immunisation is one of the most cost-effective health interventions available, preventing infection, disease, and disability around the world.[64] Indeed, "during the second half of the 20th century, vaccinations led to the control or even eradication of several vaccine-preventable diseases in Europe. However, outbreaks of vaccine-preventable diseases continue to occur even in countries with well-established vaccination programs".[65] The lingering of vaccine-preventable diseases in Europe can be attributed in some part to vaccine scepticism - vaccines are very much victims of their own success in Europe. As Plotkin argued, "In developed countries, we no longer have infectious diseases for which there are vaccines, so the risk of the vaccine is perceived to be greater than the risk of the disease. But that is true because the vaccine is being used".[66] Nowhere is this vaccine skepticism more evident in Europe than France, the source of this claim. As the The State of Vaccine Confidence 2016 survey recently attested the European region has the lowest confidence in vaccine safety with France having the least confident globally, with only with 41% of respondents in France disagreeing with the statement that "vaccines are safe" (compared to a global average of 13%).[67]

Our concern is that the judgement in *C-621/15* could contribute to this ongoing skepticism in France and the rest of Europe, or even exacerbate it. Even though the court did not find expressly that the vaccine did cause the injury suffered by Mr. W, the judgement could be read as such, particularly in light of the fact that the court approved the granting of relief to the claimants acting

[63] Case 621:15 *W and Others v Sanofi Pasteur* (n11), para 53.
[64] FE Andre, 'Vaccination greatly reduces disease, disability, death and inequity worldwide' (2008) 86 Bulletin of the World Health Organization 2, 81-160
[65] Sabine Wicker & Helena C Maltezou, 'Vaccine-preventable diseases in Europe: where do we stand?' (2014) 14 Expert Review of Vaccines 8, 979-987
[66] HJ Larson, et al. 'The state of vaccine confidence 2016: global insights through a 67-country survey' (2016) 12 *EBioMedicine,* 295-301
[67] *ibid*, P.297

on W's behalf. This can be interpreted as the court agreeing with the argument advanced by Mr W (and his next of kin) that the vaccine did cause the injury. Our concern regarding this grows when the approval of relief is taken in conjunction with Paragraph 37 which reads: "notwithstanding the evidence produced and the arguments put forward by the producer, a defect in the product appears to be the most plausible explanation for the occurrence of the damage, with the result that the defect and the causal link may reasonably be considered to be established".[68]

We accept that the CJEU, when resolving such disputes, must be mindful of the epistemological concerns of the legal process, such as applying rational procedures and achieving 'finality interests' such as conserving resources and providing repose for litigants, especially in sympathetic circumstances such as Mr W's. However, we urge the CJEU (and other institutions) to be mindful of how its decision-making can make an impact beyond individual litigants in cases involving claims about defective vaccines. Through its decision in *C-621/15* the CJEU is likely fuelling a myth: that the benefits of vaccines do not outweigh concerns about the harm they may cause. Caution should be exercised because, as Midgley has argued, "myths do not alter quickly or in a wholesale way…."[69] This is especially true where myths are attached to prominent ideas,[70] and, as the aforementioned data about vaccine scepticism suggests, vaccine scepticism is a prominent idea. The CJEU - whose decisions influence the legal frameworks of 28 member states – should be mindful to not encourage the entrenchment of such ideas without the scientific evidence-base for doing so.

IV: CONCLUSION

This Case Comment has examined the CJEU's decision in *C-621/15*. The authors have expressed three concerns about the CJEU's approach to resolving this case. First, that the CJEU improperly describes the scientific research as nether confirming nor ruling out a causal relationship between the administration of the Hepatitis B vaccine and the onset of MS. This is because the vast majority of scientific research has created a dominant theory that there is no causal link. Second, that the court improperly balances the competing scientific evidence produces in the case when it weighs circumstantial evidence, and a small number of reported cases, as equal to this body of scientific evidence thus allowing weak evidence to challenge the dominant theory. Finally, that the CJEU's approach generally feeds the growing vaccine skepticism in the developed world, and especially in France where *C-621/15* was referred from.

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[68] Case 621:15 *W and Others v Sanofi Pasteur* (n11), para 37.
[69] M Midgley, The Myths We Live By (Routledge, Oxford, 1st edn, 2004) 6.
[70] *ibid*.

Ultimately, the authors argue that the CJEU'S decision is a compelling example of the cultural conflicts that beset the institutions of law and science when they intersect in the context of legal institutions addressing scientific uncertainty. The authors argue that legal institutions, like the CJEU, when exercising their competence to address questions conflicts in science, to be mindful to not exacerbate these tensions to the detriment of 'truth.'